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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/717,226	11/19/2003	Ji-Young Kim	39894-00601	6919
29880	7590	10/17/2007		
FOX ROTHSCHILD LLP PRINCETON PIKE CORPORATE CENTER 997 LENOX DRIVE, BUILDING #3 LAWRENCEVILLE, NJ 08648			EXAMINER ROBERTS, LEZAH	
			ART UNIT	PAPER NUMBER
			1614	
			MAIL DATE	DELIVERY MODE
			10/17/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/717,226

**Applicant(s)**

KIM ET AL.

**Examiner**

Lezah W. Roberts

**Art Unit**

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 July 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 158-164, 166-202 and 205-218 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 158-164, 166-202 and 205-207 is/are allowed.
- 6) ☒ Claim(s) 208-214, 217 and 218 is/are rejected.
- 7) ☒ Claim(s) 215 and 216 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

## DETAILED ACTION

This Office Action is in response to the amendment filed July 30, 2007. All previous rejections have been withdrawn unless stated below.

The indicated allowability of claims 208-209, 212-214 and 217-218 is withdrawn in view of the newly discovered reference(s) to McAnalley et al., Frate et al. and Jenkins et al. Rejections based on the newly cited reference(s) follow.

This action is made NON-FINAL.

### *Claims*

#### **Claim Rejections - 35 USC § 102 – Anticipation (New Rejection)**

Claims 212 and 214 are rejected under 35 U.S.C. 102(b) as being anticipated by McAnalley et al. (US 5,409,703).

McAnalley et al. disclose dried hydrogel compositions comprising therapeutic agents. The dried hydrogel can be transformed to a hydrogel upon absorption of addition liquid medium (see Abstract). The hydrogel is self-adherent when wet (col. 12, lines 20-22). The compositions may be use in the oral cavity. Polymers that are used in the hydrogels include polyvinyl pyrrolidone (col. 13, lines 60-67). One example discloses Plasdane (polyvinyl pyrrolidone) and hydrogen peroxide. The hydrogen peroxide is disclosed at about 4% when the composition disclose in Table two is dried. The compositions may further comprise hydroxy ethyl cellulose. The hydrogel is placed on a sheet, which encompasses a backing layer. The reference anticipates the claims

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insofar as it discloses a dry patch comprising hydrogen peroxide and polyvinyl pyrrolidone.

**Claim Rejections - 35 USC § 103 – Obviousness (New Rejection)**

1) Claim 213 is rejected under 35 U.S.C. 103(a) as being unpatentable over McAnalley et al. (US 5,409,703) in view of Jenkins et al. (US 4,940,587).

The primary reference, McAnalley et al., is discussed above. The reference differs from the instant claim insofar as it does not disclose the compositions comprise hydroxypropylmethyl cellulose.

Jenkins et al. is used as a general teaching to show different hydroxyalkyl cellulose polymers are at times used interchangeably (as equivalents) in compositions that deliver pharmaceuticals to the mucosa of the oral cavity. These include hydroxypropylmethyl, hydroxypropyl, hydroxyethyl and hydroxymethyl cellulose (col. 2, lines 53-65). The reference differs from the instant claim insofar as it does not disclose the hydroxypropylmethyl cellulose was incorporated into compositions comprising hydrogen peroxide and polyvinyl pyrrolidone.

It is obvious to replace one component for another equivalent component if it is recognized in the art that two components are equivalent and is not based on the Applicant disclosure. See In re Ruff, 256 F.2d 590, 118 USPQ 340 (CCPA 1958); see also In re Scott, 323 F.2d 1016, 139 USPQ 297. It is also prima facie obviousness to select a known material based on its suitability for its intended use. See Sinclair & Carroll Co. v. Interchemical Corp., 325 U.S. 327, 65 USPQ 297 (1945). Also,

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established precedent holds that it is generally obvious to add known ingredients to known compositions with the expectation of obtaining their known function. See, e.g., In re Linder, 457 F.2d 506, 507 (CCPA 1972); see also In re Dial, 326 F.2d 430, 432 (CCPA 1964). It would have been obvious to one of ordinary skill in the art to have used hydroxypropylmethyl cellulose in place of hydroxyethyl cellulose as a hydrophilic material in the compositions of the primary reference based on the prior art's recognition that such species are equivalent in function, as supported by cited precedent.

2) Claims 208-211 and 217-218 are rejected under 35 U.S.C. 103(a) as being unpatentable over McAnalley et al. (US 5,409,703) in view of Frate et al. (US 2001/0049417).

The primary reference, McAnalley et al., is discussed above. In regards to claim 211, polyvinyl pyrrolidone may be considered a stabilizer for hydrogen peroxide<sup>1</sup>. The reference differs from the instant claims insofar as it does not disclose the compositions comprise a plasticizer.

Frate et al. is used as a general teaching to disclose conventional additives used in hydrogel compositions. The additives include humectants such as glycerin, propylene glycol and sorbitol (paragraph 0073). The reference differs from the instant claims insofar as it does not disclose the plasticizers are incorporated into compositions comprising hydrogen peroxide and polyvinyl pyrrolidone.

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<sup>1</sup> Breitenbach et al. (US 5,945,032) col. 1, lines 28-30

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It is *prima facie* obviousness to select a known material based on its suitability for its intended use. See *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945). Also, established precedent holds that it is generally obvious to add known ingredients to known compositions with the expectation of obtaining their known function. See, e.g., *In re Linder*, 457 F.2d 506, 507 (CCPA 1972); see also *In re Dial*, 326 F.2d 430, 432 (CCPA 1964). It would have been obvious to one of ordinary skill in the art to have incorporated a humectant such as glycerin into the compositions of the primary reference motivated by the desire to use the humectant for its specific function, as supported by cited precedent.

### ***Allowable Subject Matter***

The reason for allowance of claims 158-163, 165-202, 205-207 and 212-218 are previous discussed in the previous Office Action mailed January 29, 2007.

Claims 215-216 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 208-214 and 217-218 are rejected.

Claims 215-216 are objected.

Claims 158-164, 166-202 and 205-207 are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lezah W. Roberts whose telephone number is 571-272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lezah Roberts  
Patent Examiner  
Art Unit 1614



Frederick Krass  
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